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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

CHAKRABARTI, ARUN K

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 06/12/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/583,342

Applicant(s)

BUSHMAN ET AL.

Examiner

Arun Chakrabarti

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Detailed Action*.

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DETAILED ACTION

Specification

1. Applicant's election of Group I, corresponding to claims 1-16 and 20, in Paper No. 6 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

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3. Claims 1-16 and 20 are rejected under 35 U.S.C. 102 (e) as being anticipated by Lynch et al. (U.S. Patent 6,197,527 B1) (March 6, 2000).

Lynch et al teach a high-throughput method of screening compounds capable of modulating topoisomerase activity (Abstract and Column 4, lines 11-34) comprising:

a) incubating at least a first nucleic acid, a topoisomerase and a potential topoisomerase-modulating compound, wherein the nucleic acid comprises at least one tag (Figures 1-4 and Examples 1-3 and Column 19, lines 31-50), and

b) assaying for nucleic acid religation inherently (Figures 1-4 and Column 19, line 53 to Column 20, line 8). This inference is deduced from the fact that when a topoisomerase becomes trapped in a covalent intermediate resulting in cleavage of the nucleic acid between the two labels, the quenching is lost and an increase in signal is observed. Naturally, when there is decreased religation which is equivalent to increased cleavage, an increase in signal will be observed. On the other hand, when there is increased religation, a decrease in signal will be observed.

Lynch et al teach a high-throughput method, wherein the nucleic acid is DNA and RNA (Column 8, lines 57-62).

Lynch et al teach a high-throughput method, wherein the at least one tag is a detection tag or an affinity tag (Column 2, lines 33-44 and Column 13, line 24 to Column 14, line 63 and Column 10, lines 23-36).

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Lynch et al teach a high-throughput method, wherein the method comprises incubating at least a first nucleic acid and a second nucleic acid (Column 16, line 67 to column 17, line 10).

Lynch et al teach a high-throughput method, wherein the second nucleic acid is a religation strand comprising oligonucleotides operatively associated with at least one marker tag (Column 16, line 67 to column 17, line 26).

Lynch et al teach a high-throughput method, wherein the first nucleic acid is operatively associated with an affinity tag and the second nucleic acid is operatively associated with a detection tag (Column 16, line 67 to column 17, line 26).

Lynch et al teach a high-throughput method, wherein the assay detects for topoisomerase inhibitors and activators (Column 1, line 66 to column 2, line 2 and Column 4, lines 17-24).

Lynch et al teach a high-throughput method, wherein the topoisomerase is a Type I or Type II or Type III or Type IV isomerase (Column 16, lines 12-44).

Lynch et al teach a high-throughput method, wherein assaying comprises measuring the level of nucleic acid religation activity in the presence and absence of the topoisomerase modulating compound (Figures 1-4 and Column 19, line 53 to Column 20, line 8).

Lynch et al teach a high-throughput method, wherein the level of religation activity is inversely proportional to the effectiveness of the topoisomerase-inhibitory compound (Column 20, lines 4-8).

Lynch et al teach a high-throughput method, wherein step (a) is performed on a solid support (Figures 1, 3 and Column 15, lines 38-65 and Column 17, lines 23-63).

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Lynch et al teach a high-throughput method, wherein step (a) is performed in a liquid phase (Column 17, line 65 to Column 19, line 50).

Lynch et al teach a high-throughput method, wherein the nucleic acid and topoisomerase are covalently complexed, wherein the topoisomerase retains its religation activity (Column 15, lines 11-15 and Figure 1).

Lynch et al teach a kit for screening compounds that modulate topoisomerase religation activity comprising:

- a) a substrate nucleic acid comprising a first tag,
- b) a religation nucleic acid comprising a second tag,
- c) a topoisomerase, and
- d) a means for measuring nucleic acid religation activity of a test mixture comprising a), b) and c) in the presence or absence of a topoisomerase modulating compound (Column 2, lines 20-47 and Column 19, line 53 to Column 20, line 57).

Conclusion

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti , Ph.D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's

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supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-7401. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group analyst Chantae Dessau whose telephone number is (703) 605-1237.

Arun Chakrabarti,

Patent Examiner,

May 21, 2002


W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600